July 2007

Washington State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

Dept. of Health, PO Box 47863, Olympia, WA, 98504-7863
https://fortress.wa.gov/doh/hpqa1/hps4/pharmacy/default.htm

No. 939 Board Sets New Responsibilities Rules

The Washington State Board of Pharmacy adopted a new rule in April and amended another rule on pharmacies' responsibilities. We anticipate that these rules will be in effect mid to late July 2007. Copies of the rules can be found on the Board's Web site: *https://fortress.wa.gov/doh/hpqa1/HPS4/Pharmacy/default.htm.* The Board adopted these rules to promote patient safety. They help ensure patients have access to lawful, appropriate medications without delay. The rules outline the responsibilities of pharmacists and pharmacies in providing medicine. The rules also lay out the options a pharmacist and pharmacy have when a drug is not in stock.

The subject of these rules has prompted discussions across the country. In 2005, the Board began getting inquiries on pharmacists refusing to dispense drugs and devices because of moral or ethical objections. Washington State pharmacy laws and rules were silent on this issue.

The Board began the rulemaking process in January 2006. It considered the need for rules to define standards of patient care and professional conduct when a pharmacist's personal objections conflicted with the patient's access to legally prescribed medications.

In April 2006, the Board held stakeholder workshops in eastern and western Washington to get input for proposed rules. The Board drafted a proposal and then amended it several times during the summer based on information from the rule workshops. The Board received comments and testimony from both sides of the issue.

WAC 246-869-010 Pharmacies' Responsibilities

This rule states that pharmacies have a duty to provide legally prescribed drugs and devices, or provide a therapeutically equivalent one in a timely manner. The rule requires a pharmacy to provide patients options when a pharmacist cannot dispense.

The rule gives examples of when it may be appropriate for a pharmacy not to provide lawful prescribed drugs or their equivalent. The medicine may not be customarily needed by the pharmacy's patients or temporarily out-of-stock. The rule requires pharmacies to give patients a timely alternative when the drug is not in stock. It does not allow a pharmacy to refer a patient to another pharmacy to avoid filling the prescription due to moral or ethical objections.

The rule provides grounds for discipline when a pharmacy engages in or permits unprofessional conduct.

WAC 246-863-095 Pharmacist's Professional Responsibilities

The Board amended this rule to make it a pharmacist's primary responsibility to ensure patients get safe and appropriate medication therapy.

The amendments prohibit a pharmacist from delegating to pharmacy support staff the decision to not dispense a lawful prescribed drug or device. It provides grounds for discipline when a pharmacist, pharmacy intern, or other pharmacy employee commits or permits unprofessional conduct.

Copies of the rule language and a guidance document will be provided to each pharmacist and pharmacy in Washington State. You can also get the information at the Board's Web site: *https://fortress.wa.gov/doh/hpqa1/HPS4/Pharmacy/default.htm.* [WAC 246-869-010 and WAC 246-863-095]

No. 940 New Rule for Automated Drug Distribution Devices

At its October 2006 meeting, the Washington State Board of Pharmacy adopted a new rule to set uniform standards for the use of automated drug distribution devices (ADDDs) for all health care facilities. The rule allows facilities the flexibility to achieve outcomes with different methods.

The rule, effective December 14, 2006, includes standards for drug storage, security, and accountability. It recognizes ADDDs as appropriate storage sites for controlled substances (CS) and permits the Board to waive the end-of-shift inventory counts if the system/device can verify the accuracy of the CS counts.

Facilities must continue to submit all new policies and procedures for the use of ADDDs to the Board for review and approval. Policies and procedures must comply with the rule. They must address access, stocking, security, record-keeping discrepancies, inventory, quality assurance, and improvement programs. [Chapter 246-872 WAC]

No. 941 Pilot Program Aims to Provide Safe Options for the Disposal of Household Pharmaceutical Waste

The Board is part of a pilot program to collect and appropriately dispose of waste medications from household users. The Board has partnered with the Washington State Department of Ecology, King County Local Hazardous Waste Program, and many other agencies and nonprofit organizations. This pilot program, Pharmaceuticals from Households: A Return Mechanism (PH:ARM), intends to show the safety and effectiveness of a collection program at pharmacies over a two-year period.

The Board has worked to ensure that security measures are in place to prevent diversion of the drugs while keeping convenient public access. The Board has asked Drug Enforcement Administration (DEA) to waive existing federal law and allow approved pharmacy sites to collect unwanted CS and other medicine. This program sparked significant national attention due to the ground-

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FDA Issues Guidance on Glycerin Testing to Prevent DEG Poisoning

Spurred to action by repeated instances of diethylene glycol (DEG) poisoning, Food and Drug Administration (FDA) recently issued a guidance for industry entitled "Testing of Glycerin for Diethylene Glycol." This guidance provides recommendations on testing that will help pharmaceutical manufacturers, repackers, and other suppliers of glycerin, and pharmacists who engage in drug compounding, to avoid the use of glycerin that is contaminated with DEG and prevent incidents of DEG poisoning.

DEG contamination of glycerin can be detected by using specific analytical test procedures described in the United States Pharmacopeia monograph for glycerin, which quantifies the amount of DEG present at a detection level of 0.1%, as recommended by the interagency Diethylene Glycol Contamination Prevention Workshop of 1997. The guidance is available on the FDA Web site at *www.fda.gov/cder/guidance/7654fnl.htm.* FDA is accepting electronic comments on the guidance at *www.fda.gov/dockets/ecomments.*

Improperly Compounded Colchicine Blamed for Recent Deaths

Compounded colchicine that was 10 times as potent as labeled was responsible for two recent deaths in Oregon and Washington, the *Portland Tribune* reported on April 27, 2007. State officials are investigating the drug's role in a third death, also in Oregon. The drug was sent to a Portland, OR, clinic by ApothéCure, Inc, a Dallas, TX-based compounding pharmacy that distributes its drugs throughout the country. The two patients who died had received injections of colchicine as a treatment for back pain. Lab tests revealed that the colchicine administered in the two deaths had a potency of 4 mg/ml, rather than the 0.5 mg/ml stated on labels. According to Gary A. Schnabel, executive director of the Oregon State Board of Pharmacy, ApothéCure, a licensed Texas pharmacy, may be operating as a manufacturer. Both the Oregon Board and the Texas State Board of Pharmacy have opened investigations into the incident. The Texas Board advised ApothéCure to stop making colchicine; the company agreed, the *Portland Tribune* reported. On May 2, FDA announced the recall of all strengths, sizes, and lots of injectable colchicine compounded and sold by ApothéCure within the last year. The FDA MedWatch Safety summary on this issue is available at *www.fda.gov/medwatch/safety/2007/safety07.htm#Colchicine.*

New Podcasts Provide Emerging Drug Safety Information

FDA recently supplemented its print- and Web-based public health advisories with the launch of an audio broadcast service providing emerging drug safety information. The broadcasts, commonly known as podcasts, can be transmitted to personal computers and personal audio players. The service is part of FDA's ongoing effort to broaden and speed its communications on the safety of marketed medications when unexpected adverse events are reported to FDA. Since FDA launched the service in February 2007, broadcasts have addressed the potential hazards of local anesthetics used in hair removal; the voluntary market withdrawals of drugs to treat the symptoms of Parkinson's disease and irritable bowel syndrome; and serious adverse events associated with agents that reduce the need for blood transfusions in cancer patients. The broadcasts are available on the FDA Web site at *www.fda.gov/cder/drug/podcast/default.htm.*

Prevent Tragedies Caused by Syringe Tip Caps

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Over the past several years, there have been a number of reports where children have swallowed or choked on hypodermic syringe caps that were overlooked by parents and left on the syringes administering the medication. In 2001, a 5-month-old child asphyxiated when a cap from a Becton Dickinson 3 ml hypodermic syringe ejected into his throat during medication administration. In this case, a pediatrician provided the parents with the hypodermic syringe (without the needle) to administer Vantin® (cefpodoxime) suspension. With the cap intact, the father inserted the syringe into the Vantin, pulled back the plunger, and the medication flowed into the syringe. To him, the cap appeared to be part of the syringe. When he placed the syringe containing the medication into the baby's mouth, the cap flew off and became lodged in his airway. The baby was taken to the hospital where a procedure was performed to remove the cap; however, he did not survive.

Despite these reports, the mother of a 9-month-old child recently notified the Institute for Safe Medication Practices about a near fatal experience involving her child. Her community pharmacist gave her a parenteral syringe (without the needle) to help her accurately measure and administer an oral rehydration liquid for her daughter. Unfortunately, the pharmacist's good intention resulted in patient harm. The mother was unaware that the syringe tip held a small, translucent cap; however, despite this, she was able to withdraw the oral liquid. Then as she administered the liquid, the cap on the end of the syringe ejected and became lodged in the child's throat, causing airway obstruction. Fortunately, the child recovered.

Although parenteral syringes are not designed for oral administration, health care practitioners may provide them to patients or caregivers to measure oral liquids without realizing how dangerous this practice may be. Some syringe

manufacturers place the small, translucent caps on parenteral syringes packaged without needles as a protective cover. However, practitioners may not realize the cap is there or may not inform patients or caregivers of the need for its removal prior to use. The danger arises due to the fact that the cap does not provide a good seal. Subsequently, medications can be drawn into many of these syringes without removing the caps. If not removed before administration, the force of pushing the plunger can eject the cap and cause it to lodge in a child's trachea.

Safe practice recommendations: Consider the following strategies to help protect your patients from tragedies caused by syringe tip caps.

- **Increase awareness.** Share this and previous errors with staff to illustrate why parenteral syringes should never be used for oral liquid medications. Show staff a video from FDA and ISMP highlighting this issue (access the video link at: *www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=3#6*).
- **Product availability.** Ensure that **oral** syringes (without caps) or other appropriate measuring devices are readily available for distribution or purchase at your practice site. Verify that the dosage can be accurately measured using the oral syringe. It may be necessary to keep a few different sizes on hand to ensure proper measurement of smaller doses.
- **Limit access.** If parenteral syringes must be stocked for use with injectable products, purchase syringes that are not packaged with the translucent caps to minimize the likelihood of this error.
- **Warning labels.** Add warning labels that state, "not for use with oral liquids" to boxes or storage bins containing parenteral syringes.
- **Educate patients and caregivers.** Provide education to patients and caregivers regarding proper use of an oral syringe (or other measuring device). Demonstrate how to measure and administer the dose and inform them about how to clean the device, if it is to be reused. Several years ago, Becton Dickinson voluntarily elected to package parenteral syringes without the small caps in response to this serious issue. However, since some manufacturers still include a cap on parenteral syringes, the danger of asphyxiation with the cap is still present. We have again contacted FDA to alert them about this problem. They have stated that they will be following up with each syringe manufacturer with the goal to get the syringe caps removed. At the very minimum, we believe that the packaging of parenteral syringes should be required to clearly state, "not for oral use" or "not for use with oral liquids."

New FDA Web Page Warns Against Buying Isotretinoin Online

FDA has launched a special Web page to warn consumers about the dangers of buying isotretinoin online. Improperly used, isotretinoin can cause severe side effects, including birth defects and serious mental health problems. The Web page, *www.fda.gov/buyonline/accutane*, is positioned as a search result on Internet search engines when consumers initiate an online search for the drug under any one of its four names (isotretinoin is sold under the brand name of Accutane® and in generic versions called Amnesteem™, Claravis™, and Sotret®). The Web page warns that the drug "should only be taken under the close supervision" of a physician and a pharmacist, and provides links to related information, including ways to check that drugs purchased online come from legitimate pharmacies.

To reduce risks, FDA and the manufacturers of isotretinoin have implemented a strict distribution program called iPLEDGE to ensure that women using isotretinoin do not become pregnant, and that women who are pregnant do not use isotretinoin. Isotretinoin is available only at pharmacies that are registered for this distribution program. Additionally, the distribution program is designed to prevent the sale of isotretinoin over the Internet. Dispensing must comply with the agency's risk management requirements.

Tampering Results in Misbranding of Ziagen as Combivir

GlaxoSmithKline and FDA warned health care professionals of an apparent third-party tampering that resulted in the misbranding of Ziagen® as Combivir® and employed counterfeit labels for Combivir tablets. Two 60-count misbranded bottles of Combivir tablets contained 300 mg tablets of Ziagen.

The counterfeit labels identified are Lot No. 6ZP9760 with expiration dates of April 2010 and April 2009. The incident appears to be isolated and limited in scope to one pharmacy in California.

Pharmacists are advised to immediately examine the contents of each bottle of Combivir in their pharmacies to confirm that the bottles contain the correct medication. If a bottle contains anything other than Combivir tablets, pharmacists are advised to notify the manufacturer.

The letter from GlaxoSmithKline and FDA, containing photos of actual Combivir and Ziagen tablets, is posted on the FDA Web site at *www.fda.gov/medwatch/safety/2007/Ziagen_Dear_RPh_03-29-2007.pdf*.

FDA Issues Halt on Manufacture, Distribution of Unapproved Suppository Drugs

FDA notified health care professionals and consumers that companies must stop manufacturing and distributing unapproved suppository drug products containing trimethobenzamide hydrochloride.

These products, used to treat nausea and vomiting in adults and children, have been marketed under various names, including Tigan®, Tebamide™, T-Gen, Trimazide, and Trimethobenz. Drugs containing trimethobenzamide in suppository form lack evidence of effectiveness. This action does not affect oral capsules and injectable products containing trimethobenzamide that have been approved by FDA.

FDA urges consumers currently using trimethobenzamide suppositories or who have questions or concerns to contact their health care professionals. Alternative products approved to effectively treat nausea and vomiting are available in a variety of forms.

The MedWatch safety summary and a link to the full press release are available at *www.fda.gov/medwatch/safety/2007/safety07.htm#trimethobenzamide*.

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breaking work to include all pharmaceutical products. No other program has been implemented in the United States.

This is a pilot program with only a few operating sites. Still, nearly 1,000 pounds of waste pharmaceuticals have been collected and destroyed over the past six months. If this program were implemented statewide, 100,000 pounds of drug waste would be collected each year in Washington State. This waste would have otherwise been disposed of in the wastewater systems (toilet) and in landfills (garbage).

Our current wastewater treatment centers cannot remove many of these chemicals. Current disposal methods contaminate our lakes, streams, and wells. Additionally, the Centers for Disease Control and Prevention reports that drugs caused 94% of all unintentional and undetermined poisoning deaths in 2003.

Drug poisonings added $26 billion in medical expenses in 2000. DEA estimates that much of this drug supply is diverted for illicit use. Appropriate drug storage and disposal should lessen these social costs.

The Board has authorized seven collection pilot sites at selected Group Health Cooperative (GHC) pharmacies in Washington. You do not need to be a member of GHC to dispose of your unwanted drugs in the collection bins. If DEA grants the Board a waiver, the program will expand to 25 GHC and 35 Bartell Drug retail pharmacy sites. The pilot program plans to include a collection program for nursing homes and boarding homes.

Many pharmacies want to participate in this pilot or similar programs. The Board must receive the waiver from DEA before expanding the program. Most of the funding for the sites has been provided by local agencies and private conservation foundations. Additional funding will be needed for 2008. The PH:ARM implementation team intends to develop sustainable funding methods for a permanent statewide program.

You can contact the Board office with additional questions and find the current collection site locations on the Board Web site, or visit *www.medicinereturn.com.*

No. 942 Washington Recovery Assistance Program for Pharmacy Saves Careers and Lives

The Washington Recovery Assistance Program for Pharmacy (WRAPP) seeks to protect the health and safety of the public while acting as a health resource and support of rehabilitation to the impaired pharmacy professional. WRAPP is an employee assistance program to help pharmacy professionals who cannot competently and safely practice due to chemical dependency, emotional illness, aging, or the loss of memory or motor skills. The program provides confidential help with referrals for evaluations, treatment placements, or medical services. It contracts with individuals to monitor client progress through treatment, aftercare, rehabilitation, and re-entry into the profession.

WRAPP serves as an advocate with the practitioner, the family, the employer, and the Board to support recovery. The pharmacy Board pays for the program. There are no fees for services; however, any evaluations, treatment, or drug screens are the responsibility of the participant or the participant's insurance carrier. The identity of a voluntary participant is held in strict confidence from the Board as long as he or she complies with the terms of the WRAPP Contract.

The program is in its 24th year. It was established by the Washington State Pharmacy Association with help from the Washington State Society of Hospital Pharmacists. It has become a significant alternative to discipline. There are now 68 clients in the state of Washington: 46 are pharmacists, 19 are technicians, and three are students.

Any person who reports information on a suspected impaired practitioner to WRAPP or to the Board is immune from civil liability. Taking steps to intervene in the disease process may save not only a career, but a life. To learn how to make a compassionate but effective intervention, call WRAPP today at 1-800/446-7220. [Chapter 246-867 WAC]

No. 943 Frequently Asked Questions

Does an out-of-state nurse practitioner, naturopath, physician assistant, or optometrist have prescriptive authority in Washington State?

No. These practitioners must be licensed by the Washington State Department of Health to write prescriptions. You can verify licensure by checking the provider credential search at *https://fortress.wa.gov/doh/hpqa1/Application/Credential_Search/profile.asp.*

What is the Board's policy regarding pharmacy job shadowing?

Students in job shadowing programs must meet three conditions. (1) Be affiliated with an organized educational program. (2) Not perform any functions reserved for licensed, certified, or registered pharmacy personnel. (3) Be present in the pharmacy for a limited amount of time that does not exceed three working days. The Board also recommends that the student sign a confidentiality statement.

When must a CS inventory be performed?

A CS inventory must be performed when the pharmacy opens and **every** two years on or about the anniversary date of the last inventory. You do not have to inventory CS when there is change in the responsible pharmacy manager. However, this is a best practice.

Is an electronic signature valid when the prescription is printed and handed to the patient?

No. All printed prescriptions must be manually signed by the prescriber.

No. 944 Board Changes Policy on Pharmacy Assistant Registration and AIDS Education

Since 1998, the Department of Health has required all practitioners to complete AIDS education prior to getting health care credentials. The Board of Pharmacy has permitted pharmacy assistant applicants to work in the pharmacy up to 90 days pending the completion of AIDS education and obtaining their registration.

The Board reconsidered its previous position. All personnel must now be duly credentialed by the Board on or before working in the pharmacy. The Board changed its position because AIDS education is now more available and the Department of Health must conduct background checks on all applicants prior to credentialing.

No. 945 Pharmacy Board Needs New Members

The Department of Health is accepting applications for a public member and a professional member on the Washington State Board of Pharmacy. These vacancies are set to be filled by the governor by January 19, 2008. The Board regulates the practice of pharmacy and enforces several laws aimed at protecting and promoting public health, safety, and welfare. For more information, please contact Doreen Beebe 360/236-4834 at the Board's office or link to "Board Info" on the Board's Web page.

The *Washington State Board of Pharmacy News* is published by the Washington State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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